DETAILED ACTION

1. Claims 10 and 23-44 are all the pending claims for this application.

2. Claims 10, 25, 27, 31, 33, 39 and 41 were amended in the Response of 8/13/09.

3. Claims 10 and 23-44 are all the pending claims under examination.

4. The examiner acknowledges the telephone interview with Alexander Speigler on 9/8/09, and the telephone messages from Christopher Nichols of 9/9/09 and 9/10/09 in order to bring the application into condition for allowance.

Withdrawal of Objections

Claim Objections

5. The objection to Claim 10 because Applicants appear to have deleted a portion of the claim relating the expressed polypeptide with the phrase "at least one immunological and/or biological activity…" is moot and withdrawn. The Examiner's amendment below deletes this phrase and for reasons discussed in the attached Examiner-Initiated Interview Summary.

Withdrawal of Rejections

Claim Rejections - 35 USC § 101

6. The rejection of Claims 27, 33 and 41 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn.

Claims 27, 33 and 41 have been amended in the Response of 8/13/09 to indicate the host cell is isolated.

Claim Rejections - 35 USC § 112

Written Description

7. The rejection of Claims 10, 25-36, and 39-44 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn.

Claims 10, 25, 31 and 39 have been amended in the Response of 8/13/09 to delete the phrase "with at least 95% homology to the polynucleotide" in the Response of 8/13/09.

EXAMINER'S AMENDMENT

8. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Christopher Nichols on 9/8/09.

The application has been amended as follows:

10. (Currently Amended) A process for preparing an isolated polypeptide comprising the following steps:

(a) culturing, under suitable conditions to obtain the expression of said polypeptide, a host cell transformed or transfected with an expression vector comprising an isolated polynucleotide comprising a polynucleotide sequence of SEQ. ID. NO. 9 or SEQ ID NO. 13 ~~and having at least one immunological and/or biological activity~~

~~characteristic of a protein binding human GHRH protein and is associated with the modulation of cell proliferation~~, and

(b) isolating the polypeptide from the host cell cultures;

wherein said isolated polypeptide ~~has at least one immunological and/or biological activity characteristic of a protein binding human GHRH~~ is heterocarpine, and wherein said isolated polypeptide is associated with the modulation of cell proliferation.

25. (Currently amended) An isolated polynucleotide comprising a nucleic acid sequence of SEQ ID NO: 8, wherein said polynucleotide encodes a polypeptide ~~with at least one immunological and/or biological activity characteristic of a protein binding human GHRH protein~~ which is heterocarpine and wherein said polypeptide is associated with the modulation of cell proliferation.

31. (Currently amended) An isolated polynucleotide comprising a nucleic acid sequence of SEQ ID NO: 9, wherein said polynucleotide encodes a polypeptide ~~with at least one immunological and/or biological activity characteristic of a protein binding human GHRH protein~~ which is heterocarpine and wherein said polypeptide is associated with the modulation of cell proliferation.

39. (Currently amended) An isolated polynucleotide comprising a nucleic acid sequence of SEQ ID NO: 13, wherein said polynucleotide encodes a polypeptide ~~with at least one immunological and/or biological activity characteristic of a protein binding~~

~~human GHRH protein~~ which is heterocarpine and wherein said polypeptide is associated with the modulation of cell proliferation.

Examiner's Statement of Reasons for Allowance

9. The following is an examiner's statement of reasons for allowance:

Heterocarpine protein is encoded by the fragment of the polynucleotide sequence SEQ. ID. NO. 8 contained between the bases at positions 115 (initiation codon ATG encoding for a methionine) and 2437 (stop codon UAA), i.e. by the polynucleotide sequence SEQ. ID. NO. 9; or by the polynucleotide sequence of SEQ ID NO:13 which corresponds to the sequence SEQ. ID. NO. 9 having artificially undergone deletion of the initiation codon ATG in order to allow the expression of recombinant heterocarpine from the pQE-TriSystem (Qiagen) phase vector with the BamH 1 site as well as deletion of the stop codon in order to preserve the phase translation to protein and thus allow the synthesis of an 8xHis sequence in the C-terminal region of heterocarpine. The primers used to generate the polynucleotides encoding the heterocarpine protein were of SEQ ID NOs: 4, 5, 11 and 12. The polynucleotides are free from prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

10. Claims 10 and 23-44 are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lynn A. Bristol/
Examiner. Art Unit 1643
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